UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF TORRENT-SPECIFIC MOTIONS *IN LIMINE* FOR THE TPP TRIAL

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules

INTRODUCTION

Throughout this case, Plaintiffs have consistently resorted to misleading and prejudicial tactics to make up for the lack of evidence to support their claims. For example, Plaintiffs have repeatedly misquoted the word "cheaper" as "cheap," cherry-picked lines from emails, misattributed quotes, and used unnecessarily inflammatory language in a clear attempt to cast Defendants Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. ("Torrent") in a bad light. Despite multiple meet and confers, Torrent has been unsuccessful in convincing Plaintiffs to change course for trial. This Court's intervention is necessary to ensure Torrent receives a fair trial. Torrent therefore respectfully moves *in limine* to preclude Plaintiffs from introducing at trial any evidence, testimony, or argument referencing the topics set forth below.

ARGUMENT

I. THE MERIDAN REPORT SHOULD BE EXCLUDED.

This Court should exclude the report issued by Meridan Consulting LLC ("Meridan") in May 2020 regarding Torrent's investigations of out-of-specification results affecting non-Valsartan products (the "Meridan Report"). Ex. 1, TORRENT-MDL2875-00433346.

First, the Meridan Report has no relevance in this case. Fed. R. Evid. 401; Fed. R. Evid. 402. In October 2019, the FDA issued a Warning Letter requesting

that Torrent hire a third-party consultant to [redacted]. Ex. 1 at 8-9. Torrent hired Meridan to conduct that review. In May 2020, Meridan issued its report making detailed findings [redacted] Ex. 1 at 2-3. The Meridan Report makes [redacted]. Ex. 1 at 8-9. Audit findings unrelated to VCDs do not "have any tendency to make a fact of consequence in this action 'more or less probable,'" and should therefore be excluded. *See Krys v. Aaron*, 2015 WL 3857085, at *3 (D.N.J. June 22, 2015) ("this Court cannot conclude that . . . auditing problems unrelated to [the funds at issue] have any tendency to make a fact of consequence in this action 'more or less probable'").[1] And Meridan's review was conducted between November 2019 and January 2020—*i.e.*, more than a year after the recall of Torrent's VCDs. Investigations "conducted outside [the relevant] time

[1] *See also Copeland v. Metro. Atlanta Rapid Transit Auth.*, 2011 WL 13174550, at *3 (N.D. Ga. May 3, 2011) (precluding evidence of the "justification[] for the internal affairs investigation" because it was "unrelated and irrelevant" to the claim at issue); *Sabre Int'l Sec. v. Torres Advanced Enter. Sols., LLC*, 72 F.Supp.3d 131, 144 (D.D.C. 2014) (excluding evidence of "an audit . . . that is unrelated to this case"); *Erickson v. Biogen, Inc.*, 2019 WL 2525424, at *3 (W.D. Wash. June 19, 2019) ("Any information related to other . . . investigations is unrelated to Plaintiff's claims and irrelevant.").

period are irrelevant" and should not be admitted. *Zimmerman v. Schaeffer*, 2009 WL 5111765, at *8 (M.D. Pa. Dec. 16, 2009) (excluding audit from one year after relevant time period).

Second, any minimal probative value of such evidence is substantially outweighed by the danger of unfair prejudice, confusing the jury, and wasting time at trial. Fed. R. Evid. 403. The only purpose Plaintiffs could have for using the Meridan Report is to create a false narrative of negligent manufacturing practices at Torrent, hoping that the jury will speculate and draw negative inferences as to Torrent's VCDs based on totally unrelated conduct. Not only will this false narrative prejudice Torrent at trial, it will also waste limited trial time on an irrelevant document that will undoubtedly confuse and mislead the jury. *See Krys*, 2015 WL 3857085, at *3 ("unrelated . . . auditing problems may mislead and confuse the jury and unfairly prejudice Defendants, while consuming undue time compared with the probative value, because their introduction might lead the jury to impugn the propriety of Defendants' actions with respect to [funds at issue] as a result of their conduct with respect to other [unrelated] funds").

This is exactly what happened during Sushil Jaiswal's deposition. Plaintiffs repeatedly speculated that the manufacturing of VCDs must have been affected by the same issues identified by Meridan with respect to other drugs.[2] That wasteful

[2] Ex. 2, 6/25/2021 S. Jaiswal Tr. at 986:7-19 ("[redacted]

line of questioning went on over 40 pages of the deposition transcript, with Plaintiffs combing through the Meridan Report. *See* Ex. 2, S. Jaiswal Tr. at 951-994. This is precisely the type of prejudicial side-show that Rule 403 was designed to prevent.

Finally, the Meridan Report constitutes inadmissible evidence of subsequent remedial measures pursuant to Federal Rule of Evidence 407. As detailed above, Torrent hired Meridan to remedy the observations contained in the FDA's Warning Letter. Courts routinely exclude such evidence of remedial measures when used to prove that a defendant's conduct is culpable. *See, e.g.*, *Complaint of Consolidation Coal Co*., 123 F.3d 126, 136 (3d Cir. 1997) (upholding exclusion of investigation memo because "there is authority supporting the exclusion of evidence of post-accident investigations under Rule 407"); *Nance v. City of Newark*, 2010 WL 2483747, at *4 (D.N.J. June 4, 2010) (excluding references and evidence regarding investigative findings because it "would constitute subsequent remedial measures . . . and would likely be inadmissible under Fed. R. Evid. 407"); *Brady v. Zimmer, Inc*., 2015 WL 2092850, at *3 (D.N.J. May 4, 2015) (excluding subsequent

[redacted]).

investigative findings that sales of the medical device should be "suspended" and that "surgeons" should receive "additional training" because such evidence of "[s]ubsequent remedial measures . . . are not relevant to the claims at issue in the matter, and may not be used as proof of . . . culpable conduct"). Otherwise, companies like Torrent would be deterred from taking remedial actions to improve their business.

II. REFERENCES TO "CHEAP" CHINESE API SHOULD BE EXCLUDED.

Plaintiffs erroneously assert that Torrent put profits before safety, misquoting a phrase in a single email as confirming their theory. Ex. 3, TORRENT-MDL2875-00005763. While the email uses the phrase "[redacted]," *id.*, Plaintiffs routinely and intentionally misquote the phrase as "[redacted]."[3] The Court should preclude any reference to ZHP's active pharmaceutical ingredient ("API") as "cheap," because any probative value would be substantially outweighed by the

[3] *See, e.g.*, ECF No. 2569-1 at 1 ("The defendant manufacturers of valsartan, a medication to treat high blood pressure, elevated their pursuit of market share and profit to an unsafe and reprehensible level, and in order to do so they abrogated their fundamental obligations to protect the safety of the intended patient population."); Ex. 4, 10/31/2022 Russ Rpt. ¶ 106 (noting that Torrent was discouraged from questioning the quality of ZHP's API for fear of losing access to its source of "cheaper Chinese API"); Ex. 5, 4/14/2021 K. Gegenheimer Tr. at 396:3-10 ("I'm a little concerned by where you are leading me with this. Because I -- you're using the term 'cheap,' it almost sounds like . . . there's a problem with it. To me, cheap is . . . a low cost of goods").

danger of unfair prejudice and misleading the jury. Fed. R. Evid. 403.

Plaintiffs' premise that low-cost goods are produced by cutting corners in terms of safety is wrong, and Plaintiffs should not be allowed to falsely equate "cheap" with "dangerous." The manufacturing of both API and finished dose drugs is heavily regulated and subject to FDA approval. Ex. 5, K. Gegenheimer Tr. 398-99. At most, the phrase [redacted] conveys Torrent's desire to reduce its costs and fully participate in the low-margin, ultra-competitive generic drug market. In this instance, Torrent hoped its low prices would allow it to win [redacted]'s business. Ex. 3 ("[redacted]"). Such behavior is not nefarious. Any reasonable for-profit company like Torrent seeks to reduce costs and increase profits to survive in a global economy.

Courts routinely prohibit the use of certain pejorative words or phrases at trial that are, on balance, prejudicial, irrelevant, or unhelpful to the jury. *See, e.g.*, *Finjan, Inc. v. Blue Coat Sys., Inc.*, 2015 WL 4129193, at *2 (N.D. Cal. July 8, 2015) (court permitted "neutral, factual statements" about party's business but excluded "derogatory or misleading characterizations about [that] business"); *In re Loestrin 24 Fe Antitrust Litig.*, 2019 WL 13257216, at *4 (D.R.I. Dec. 6, 2019) (precluding plaintiffs "from using any pejorative terms" like "payoff" or "kickback" that are "intended to inflame the jury"). The same thing can be said about Plaintiffs' use of the phrase [redacted] to suggest that producing low-cost goods means

Torrent ignored quality or safety—the phrase is a "derogatory or misleading characterization" that has the potential of inflaming and misleading the jury. *Finjan*, 2015 WL 4129193, at *2. This is particularly true given that Plaintiffs deliberately misquote this email as "[redacted]" to suggest that cheap equated to low quality. *See* Ex. 5 at 395-399; Ex. 6, 6/4/2021 S. Jaiswal Tr. at 151, 200; Ex. 7, 5/13/2021 D. Chitty Tr. at 233; Ex. 8, 2/22/2021 J. Rivera Tr. at 76-78. The Court should preclude Plaintiffs from continuing to misquote the phrase "[redacted]" as "[redacted]."

III. EVIDENCE AND ARGUMENT THAT TORRENT'S ACTIONS WERE FINANCIALLY MOTIVATED SHOULD BE EXCLUDED.

On many occasions, Plaintiffs have attacked Torrent's recall process as financially motivated. For example, Plaintiffs alleged in their operative complaint that "Defendants failed to recall their generic VCDs because they feared permanently ceding market share to competitors," until "the FDA had threatened an involuntary recall." ECF No. 1708 ¶ 402.[4] Plaintiffs' summary judgment motion likewise asserted that Torrent's actions "were driven by fear of losing profits, with no regard for the rights of those paying for the contaminated valsartan." ECF No. 2558-1 at 2. But Plaintiffs' sweeping assertion of improper motive rests entirely on

[4] This is particularly untrue with respect to Torrent because the FDA never threatened Torrent with an involuntary recall.

two inadmissible, cherry-picked quotes. Once these inadmissible statements are properly excluded (as explained below), Plaintiffs have no leg to stand on. This Court should thus bar Plaintiffs from continuing to baselessly assert that Torrent had an improper motive during the time period from ZHP's first notification of a potential contamination to the recall of its products. Fed. R. Evid. 901.

A. July 5, 2018 Email

Plaintiffs point to a July 5, 2018 email that states: "[redacted]." Ex. 9, TORRENT-MDL2875-00090454 at -58. Based on that single quote, Plaintiffs allege that "ZHP ***and*** Torrent . . . discussed minimizing lost profits as a result of the contamination." ECF No. 2558-1 at 2 (emphasis added). However, this quote should be excluded because it lacks any foundation and cannot be attributed to Torrent. Fed. R. Evid. 901. Instead, as the email makes clear, Torrent employee Dhrumit Shah was sharing a message ***from ZHP*** with others at Torrent, saying this was a "[redacted]." Ex. 9 at -58; *see* Ex. 10, 3/16/2021 D. Shah Tr. at 336:6-7 ("[redacted]."). Nor does Mr. Shah understand what ZHP meant when it

said it hoped to "minimize the impact to our products and the market." *Id*. at 335-37.[5]

B. July 18, 2018 Email

Plaintiffs also rely on a July 18, 2018 email stating: "[redacted] [.]" ECF No. 2558-1 at 2 (quoting Ex. 11, TORRENT-MDL2875-00072542). This quote is likewise inadmissible and should be excluded because Plaintiffs will not be able to establish foundation at trial. Fed. R. Evid. 901. The author of this statement, Arunesh Verma, was not deposed and no longer works at Torrent, and Plaintiffs have not taken any steps to compel him to appear.[6]

---

[5] Additionally, even if that quote could somehow be attributed to Torrent (it cannot), Plaintiffs' use is misleading and should not be permitted at trial. Fed. R. Evid. 403. Rather than revealing an intent of prioritizing profits, it shows a genuine concern for doing the right thing. In the very same message, [redacted] Ex. 9 at -58. And, tellingly, despite Plaintiffs' suggestion, the word "profits" appears nowhere in the email thread. Plaintiffs should not be able to use this sentence to suggest that Torrent "discussed minimizing lost profits as a result of the contamination." ECF No. 2558-1 at 2.

[6] Plaintiffs (again) use this quote in a misleading way. Fed. R. Evid. 403. Plaintiffs conveniently fail to quote the end of Mr. Verma's sentence: ". . . [redacted]." Ex. 11 at -42. Mr. Verma's desire was ***not*** to continue selling Torrent's VCDs and delay a recall. Instead, he wanted to put an end to the uncertainty that prevailed at the time as to whether Torrent's VCDs contained nitrosamines. If that could be ruled out quickly, then Torrent would be able to restart production and supply its customers.

* * *

For the reasons noted above, Plaintiffs should not be allowed to introduce the above-mentioned quotes or argue that Torrent's recall process was driven by "fear[] [of] permanently ceding market share to competitors," ECF No. 1708 ¶ 402, or "fear of losing profits, with no regard for the rights of those paying for the contaminated valsartan." ECF No. 2558-1 at 2.

IV. EVIDENCE AND ARGUMENT THAT TORRENT SHOULD HAVE RECALLED ITS VCDS IN JUNE 2018 SHOULD BE EXCLUDED.

This Court should exclude any evidence or argument that Torrent should have recalled its VCDs as early as June 20, 2018—*i.e.*, when it first received a notification from ZHP that it "[r]ecently . . . came to be aware of a previously unknown impurity that may have genotoxic potential"[7]—instead of on August 17, 2018. *See, e.g.*, ECF No. 2563 ¶¶ 9-21. Any presentation of that baseless theory at trial could only serve to mislead, confuse, and inflame the jury. It is therefore barred by Federal Rule of Evidence 403. *See Bosley v. DePuy Synthes Sales Inc.*, 2023 WL 6460613, at *2 (W.D. Wash. Oct. 4, 2023) (excluding of evidence of a delayed recall because it would be highly prejudicial and would depict the defendant as a bad corporate actor); *Bosley v. DePuy Synthes Sales Inc.*, 2:21-cv-01683-MLP, ECF No. 88, at 7 (W.D. Wash. Aug. 29, 2023).

[7] Ex. 12, TORRENT-MDL2875-00159677.

At the core of Plaintiffs' misleading theory is Dr. Jaiswal's testimony. *See* ECF No. 2563 ¶¶ 9-21 (citing Dr. Jaiswal's deposition thirteen times). But rather than proving their theory, Dr. Jaiswal's testimony disproves it. As Dr. Jaiswal and others testified, until the FDA told Torrent on August 16, 2018 that its VCDs contained nitrosamines, Torrent lacked the information necessary to recall its VCDs. The timeline of events leading up to Torrent receiving that information from the FDA is:

- **June 20, 2018:** "Torrent placed its valsartan on hold." *Id.* ¶ 10 (citing S. Jaiswal Tr. at 226:17-19 ([redacted]); *see also* Ex. 13, TORRENT-MDL2875-00099932.
- **June 26, 2018:** ZHP informed Torrent that only API manufactured with the "New Process" (*i.e.*, zinc chloride process) contained nitrosamines, whereas Torrent's VCDs sold in the U.S. exclusively used "Old Process" API (*i.e.*, TEA process). ECF No. 2563 ¶ 11 (citing S. Jaiswal Tr. at 227:3-228:1); *see also* Ex. 14, TORRENT-MDL2875-00523107; Ex. 15, TORRENT-MDL2875-00523106.
- **July 2, 2018:** Torrent began developing its own testing method for nitrosamines. Ex. 23, TORRENT-MDL2875-00142942.
- **July 18, 2018:** According to the FDA, no market action was required based on the information provided by ZHP, and Torrent could continue selling its VCDs in the U.S. Ex. 6 at 228:8-230:9; Ex. 16, TORRENT-MDL2875-00005188.
- **August 3, 2018:** ZHP notified Torrent for the first time that "Old Process" API also contained nitrosamines. ECF No. 2563 ¶ 15 (citing TORRENT-MDL2875-00131255). But Torrent could not confirm which ZHP batches were impacted, whether those batches had been sold to Torrent, and, if so, what the levels of nitrosamines in those API batches were, because ZHP's notification did not contain that information, and because Torrent still had not finished developing its testing method. Ex. 7 at 290-93, 309-10. That meant Torrent could not, in consultation with the FDA, yet assess whether a recall of Torrent's VCDs was appropriate. *Id*. at 296, 309-310.
- **August 14, 2018:** Torrent continued to develop its method for detecting nitrosamines in its VCDs. Ex. 17, TORRENT-MDL2875-00087628.

- **August 16, 2018:** FDA first confirmed that nitrosamines were present in Torrent's VCDs. ECF No. 2563 ¶ 16; Ex. 18, TORRENT-MDL2875-00520737.
- **August 17, 2018:** Torrent initiated a recall of its VCDs. Ex. 19, U.S. Food and Drug Admin., *Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Valsartan/Amlodipine/HCTZ Tablets* (Aug. 17, 2018), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-valsartan-amlodipine-hctz-tablets.

Contrary to the undisputed timeline, Plaintiffs vaguely suggest that Torrent could have tested its VCDs as early as June 20, 2018, but chose not to. ECF No. 2563 ¶ 10. Any such suggestion would only confuse the jury. At the time the VCDs were approved by the FDA, and continuing through the time of the recalls beginning in July 2018, there were no validated or industry-standard methods or practices to test for the presence or absence of NDMA or NDEA in VCDs.[8] Developing a new method to test for nitrosamines in a particular product "[redacted]" because the method "[redacted]" needs to be "[redacted]." Ex. 6 at 237:2-23. ZHP—the DMF holder—initially agreed to share its method, but ZHP's method proved to be [redacted] Ex. 22, TORRENT-MDL2875-00072713 at -15. Nonetheless, Torrent did not remain idle and began developing its own testing methodology as early as

[8] Ex. 20, 1/11/2023 Afnan Rpt. ¶ 182 ([redacted]."); Ex. 21, U.S. FOOD AND DRUG ADMIN., Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by GC/MS-Headspace (Jan. 28, 2019), https://www.fda.gov/media/117843/download.

July 2, 2018—a process that took (as expected) several weeks and was not completed at the time of the recall. Ex. 6 at 245:5-8; Ex. 17; Ex. 23, TORRENT-MDL2875-00142942. The FDA itself also had to develop its own method and did not share it with Torrent prior to its recall. Ex. 22 at -216 ("[redacted].").

Permitting Plaintiffs to present their theories regarding a June 20, 2018 recall by Torrent would also mislead the jury by falsely suggesting that the only thing Torrent could do after receiving ZHP's June 20, 2018 notification was to recall all products from the market. That is not what the FDA recommended. In fact, the FDA greenlit Torrent's VCDs on July 16, 2018, and determined that they contained nitrosamines only on August 16, 2018. Ex. 16; Ex. 18. And, crucially, drugs must not be recalled unless one has "[redacted]," or else it could lead to shortages depriving patients of their life-saving medicines and have far worse consequences. Ex. 7 at 318:8-9; *id*. at 317-18, 436-437.[9] The misleading

[9] *See also* Ex. 24, 2/9/2023 A. Nagaich Tr. at 94-95; Ex. 25, U.S. Food and Drug Admin., *Product Recalls, Including Removals and Corrections: Guidance for Industry* (Mar. 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections (recommending that drug manufacturers inform the FDA of their recall strategy, state whether the proposed "recall will create a market shortage that may impact consumers," and "provide any draft plan to address the shortage").

nature of Plaintiffs' theory regarding a June 20, 2018 recall is sufficient alone to exclude that theory pursuant to Federal Rule of Evidence 403.

But this theory should further be excluded because it is highly and unfairly prejudicial to Torrent. The history of this case reveals that Plaintiffs intend to use this baseless theory that Torrent "delayed" its VCD recall to unfairly and inflammatorily portray Torrent as a dangerous corporation that prioritizes money over safety. Plaintiff did so throughout depositions of Torrent witnesses.[10] Absent the Court's intervention, Plaintiffs are likely to repeat this at trial, with the sole purpose of painting Torrent as "a bad corporate actor that prioritized financial gain over consumer safety" and winning its case based on prejudice rather than on the merits. *T.G. v. Remington Arms Co.*, 2014 WL 2589443, at *6 (N.D. Okla. June 10, 2014). Rule 403 exists precisely to prevent such a trial strategy.

[10] *See, e.g.*, Ex. 6 at 246:19-251:22 ("[redacted]").

V. EVIDENCE AND ARGUMENT THAT TORRENT DID NOT ADDRESS THE CONCERNS RAISED BY DR. YANG SHOULD BE EXCLUDED.

As part of their allegations that Torrent violated current Good Manufacturing Practices ("cGMPs"), Plaintiffs focus on a September 23, 2015 email from Dr. Jenny Yang (an auditor hired by Torrent to audit ZHP's manufacturing facilities), in which she points to [redacted] Ex. 26, TORRENT-MDL2875-00124209. Based on that email, Plaintiffs' cGMP expert Philip Russ asserts that "[redacted]." Ex. 4 ¶ 119. The Court should exclude Dr. Yang's September 23, 2015 email and preclude Plaintiffs from arguing that Torrent did not respond to or act upon Dr. Yang's concerns.

First, Dr. Yang's September 23, 2015 email should be excluded because it is irrelevant. Fed. R. Evid. 401; Fed. R. Evid. 402. This email can be relevant only to Plaintiffs' claim that Torrent falsely represented that its VCDs were manufactured in compliance with cGMPs. *See* ECF No. 1708 ¶¶ 623-24, 628, 630 (First Cause of Action), ¶¶ 691-94 (Fifth Cause of Action), ¶¶ 727-28, 731-32 (Seventh Cause of Action). Indeed, Mr. Russ relied on this email in support of his conclusion in his report that "[redacted]." Ex. 4 ¶¶ 119-120. But Mr. Russ subsequently admitted during his deposition that this email

cannot support a cGMP violation, explaining that [redacted]" and that any response to this email would be "[redacted]." Ex. 27, 1/5/2023 P. Russ Tr. at 304:15-305:25. To matter under cGMPs, Dr. Yang's concerns would have had to be formalized in an audit report, which would have triggered the "Corrective and Preventive Action" mechanism and required Torrent and ZHP to resolve the concern to the auditor's satisfaction. *Id.* Thus, by Plaintiffs' own admission, this email is irrelevant to establishing a cGMP violation.

Second, allowing Plaintiffs to assert that Torrent failed to comply with its auditing obligations under cGMPs based on Dr. Yang's email creates a serious risk of misleading the jury. Fed. R. Evid. 403. Rule 403 forbids Plaintiffs from making demonstrably false and factually unsupported assertions. *See, e.g.*, *In re Prempro Prod. Liab. Litig.*, 2006 WL 3806391, at *7 (E.D. Ark. Dec. 27, 2006) (holding that the plaintiff could not "assert that certain doses are no longer approved by the FDA, since that statement is inaccurate"); *Young v. Smith*, 2016 WL 3522965, at *8 (M.D. Pa. June 28, 2016) ("where Plaintiff's method of proof inappropriately . . . introduc[es] evidence that is meant to confuse the jury [and] that invites false inferences . . . it is this Court's province under Federal Rule of Evidence 403 to put an end to such tactics").

Defendants anticipate that Plaintiffs will rely on Dr. Yang's email to mislead the jury into believing that Torrent "[redacted]" as Mr. Russ asserts. Ex. 4 ¶ 119. But Plaintiffs have no evidence to support this assertion (tellingly, Mr. Russ cites none), and thus should not be allowed to mislead the jury on this point. Indeed, the evidence shows the opposite is true: Torrent addressed all of Dr. Yang's concerns.[11] During his deposition, Dr. Jaiswal explained that vendors such as ZHP must submit close out reports of their corrective and preventive actions in response to any follow ups from an auditor, without which the audit process is not deemed to be closed. Ex. 29, 6/5/2021 S. Jaiswal Tr. at 500:1-501:14. And here, there is no evidence suggesting that this particular audit was not closed. In sum, Torrent having closed out the audit process is direct evidence of Torrent having addressed all of Dr. Yang's concerns, and thus any evidence or argument that Torrent ignored Dr. Yang's concerns should be excluded.

CONCLUSION

For foregoing reasons, Torrent respectfully requests that the Court grant Torrent's motions *in limine*.

[11] Notably, when Plaintiffs were given the opportunity to depose Kalpesh Patel—who was actually forwarded Dr. Yang's email—they did not ask him any questions about Torrent's response to that email. Ex. 28, K. Patel Tr.

Dated: February 16, 2024

Respectfully Submitted:

By: */s/ Alexia R. Brancato*

KIRKLAND & ELLIS LLP
Devora W. Allon
Alexia R. Brancato
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
Fax: (212) 446-6460
Devora.allon@kirkland.com
Alexia.brancato@kirkland.com

Attorneys for Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.

CERTIFICATE OF SERVICE

I, Alexia R. Brancato, an attorney, hereby certify that on February 16, 2024, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF and caused the unredacted version filed under seal to be served on all counsel of record by email.

/s/ Alexia R. Brancato
Alexia R. Brancato
Kirkland & Ellis LLP